

Clinical Center News

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Daniels named chief of pharmacy at CC

Dr. Charles E. Daniels (above) has been named chief of the CC Pharmacy Department effective October 1.

Senior associate director of pharmacy at the University of Minnesota Hospital and Clinic since 1992, the California native had also served as associate director of pharmacy there. He has been assistant professor of pharmacy at the University of

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CC department instrumental in start of four gene-therapy protocols

As the Clinical Center undergoes unprecedented scrutiny of its mission and operations, remarkable things continue to occur within its walls. During a recent six-week period, the CC's Department of Transfusion Medicine (DTM) started four patients on four different gene-therapy protocols from four institutes.

Would this have been possible anywhere else? "No place that I'm aware of," according to Dr. Harvey Klein, DTM chief. "We have outstanding collaborations with the institutes, so that we're on the cutting edge of where transfusion science is going," he explains. "No other transfusion service or blood bank in the world has access to the research resources that are available to us here."

The four protocols are for chronic granulomatous disease (CGD); Fanconi anemia; Gaucher disease; and the multiple-drug-resistance gene in cancer. Also, the two young girls who received the first gene therapy at the CC in 1990 visit regularly for treatments. Says Dr. Klein, "After we treated the first two patients in 1990, we expected to get maybe one or two protocols a year, when in fact we got none. We had some gene-marking protocols, but no therapeutic protocols."

Over the past year, however, things heated up. One by one,

researchers brought their gene therapy specifications to DTM staff. Questions were answered. Innumerable details were tended to. Target treatment dates were set, far enough apart so that everything for patient 1 would be out of the laboratory in time to refocus for patient 2.

Or so they thought.

"It was strictly by chance that all these investigators got their techniques, approvals, and patients together at about the same time," says Dr. Klein. "We certainly hadn't expected it to happen that way, but we were fully prepared for each one."

How does DTM treat all these gene therapy patients at the same time without getting things mixed up? "Blood banks are incredibly meticulous about things like labeling, storage, and issue of components," explains Dr. Klein. "Two people check everything." So it was second nature to DTM to apply these rigorous procedures to the specially modified cells used in gene therapy.

Dr. Harry Malech, NIAID principal investigator on the CGD trial, reflects on the CC's role in this research milestone: "It isn't that I couldn't do [this work] as well; I just could not do it without all these units at the Clinical Center working together."

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Interns graduate

The Nutrition Department graduated its third class of dietetic interns this summer. They were (from left) Patricia Bannan, a graduate of the University of Delaware and 1995 recipient of the Edith A. Jones scholarship; Susan Hippchen, University of Maryland graduate; Jennifer Galasso, who earned the B.S. at Pennsylvania State and a master's from Drexell; and Shanna Cozart, a Kansas State grad. The graduates will sit for the national dietetics registration exam next month.



answers

(Editor's note: Dr. John I. Gallin, CC director, asked employees to send him job-related concerns and questions. CCNews will print Dr. Gallin's responses in a periodic series that continues this month.)

Comment: Invest time, energy and resources in your managers at all levels. Performance management is key in changing our practices. Also, reorganizing structure to patient-focused care would encourage efficiencies, performance management, and accountability for all. Managers here are ready, willing, and able to honestly and efficiently manage downsizing, fiscal resources, and even writing ourselves out of a job if improved patient care means a unit reorganization. The frustration is the "permission" to become involved isn't forthcoming from "above."

Response: The Clinical Center is indeed staffed with a capable, dedicated, innovative cadre of managers who have proven their abilities to be effective, flexible, and responsive time and time again. And we plan to continue to encourage growth of managers professionally through current and future

educational opportunities.

The expertise and support of managers are especially needed now. I encourage all staff to make their ideas, suggestions, and concerns known to me or to Dr. Helen Smits, who chairs the Options Team. Her e-mail address is hsmits@nih.gov. Mine is jgallin@nih.gov.

Comment: I love this place and will work hard to preserve the genuine caring and high quality of performance here. Because of the "no-charge-to-patients" environment here, I see an incredible waste and misuse of materials in the inpatient areas. I suggest having a task force tackle this problem and to educate staff about the financial, environmental, and social impacts of careless use of supplies.

Response: Your suggestion to examine waste and misuse of materials is a good one, one that the Options Team will explore. The issue

of charging patients and the impact this might have on efficiencies is interesting and complex. The Inspector General has suggested we "charge patients" through collection from private insurers. This proposal is under review.

Comment: The CC relies on NIH for its utilities, engineering, and logistics support. Their inefficiencies are passed on to the CC. Is the Options Team looking at ways to reduce these charges by support services? Can utility rates be bench marked with comparable facilities?

Response: The team is looking at the possibility of reducing NIH support services charges to the Clinical Center, and there is a bench marking subcommittee that will examine the rate issue. Bench marking is, literally, a standard or point of reference for measuring or judging quality or value. It's important that we look to other government and nongovernment entities to find the best ideas they have to adapt for use here.

Clinical Center
News

Editor: Sara Byars

Clinical Center News, Building 10, Room 1C255, National Institutes of Health, Bethesda, Maryland 20892. (301) 496-2563. Fax: 402-2984. Published monthly by the Office of Clinical Center Communications, Colleen Henrichsen, chief, for CC employees. News, article ideas, calendar events, letters, and photographs are welcome. **Deadline** for submissions is the second Monday of each month.

PT Day features hands-on health care

"Hands-On Health Care" is the theme for the Oct. 5 Physical Therapy Day sponsored by Rehabilitation Medicine Department's physical therapy section. The event, which will include a hot dog sale, crutch races, and prizes, will be held in front of building 31A from 11 a.m.-1:30 p.m. Displays will include specialty chairs, desks, and other equipment designed to maintain a healthy back. For those with pain from golf swings, tennis elbow, carpal tunnel syndrome, or any other activity, physical therapists will offer free advice.

AOs change

Barbara Young has assumed duties as administrative officer (AO) for the Department of Diagnostic Radiology. She was formerly AO for the CC Office of the Director. Linda Ray will act as interim AO for the Clinical Center director's office in addition to her duties in that capacity for the Nuclear Medicine Department.

Classes on tap

The education and training section, Office of Human Resources Management, will offer the following classes in October as part of a five-week series "Taking Action: Being Assertive When it Counts":

- Your Communication Style During Stress and Conflict, Oct. 11.
- Proactive Listening, Oct. 18
- Decreasing the Intensity of an Interaction, Oct. 25.

Classes are held noon-1:30 p.m. in room B1C22. Call 496-1618 to register.

Medical writer featured Sept. 28

Internationally acclaimed medical writer and author of the best-selling book *The Coming Plague*, Laurie



CC to recycle

The Clinical Center will initiate a paper recycling project on Oct. 1.

"We'll collect white office paper initially," explains Hank Primas, Housekeeping and Fabric Care Department chief and project coordinator for the CC. "The NIH Division of Safety will provide individual and area collection boxes. We'll phase in project participation, beginning with offices on the CC's first and second floors."

Recycling is a sound idea environmentally and fiscally, he points out. "The CC has to pay \$125 for each ton of waste taken to local landfills, but can actually earn money for each ton of white paper we collect for recycling."

Garrett, was in Kikwit, Zaire, during the height of the most recent Ebola virus outbreak. She'll talk about her experiences at noon on Thursday, Sept. 28, in Masur Auditorium. The presentation is sponsored by the NIH Division of Safety, Office of Research Services.

Garrett, whose coverage of

emerging infectious diseases has ranged from human encounters with exotic viruses in the rain forest to drug-resistant tuberculosis in American inner cities, earned an undergraduate degree in biochemistry and was a Ph.D. candidate in immunology before beginning her career in journalism. She was science correspondent for National Public Radio for eight years, currently is on the staff of *Long Island Newsday*, and is president of the National Association of Science Writers. For more information, call Dr. Deborah Wilson at 496-2960.

Cholesterol tests offered this month

Keeping your heart and blood vessels healthy means caring enough to learn what your blood cholesterol level is and doing something about it if it's high. September—National Cholesterol Education Month—is a good time to start. At NIH the cholesterol screening program is sponsored by the Occupational Medical Service in cooperation with the R&W Association and NHLBI.

Clinical Center staffers can stop by room 6C306 on Sept. 5, 12, 19, and 26 between 7:30 and 10:30 a.m. for the simple blood test. Those who want a test must not eat or drink anything except water for nine hours prior. The test costs \$11.50. OMS routinely offers screening in building 10, Tuesdays 8-11 a.m. Call 496-4411 for details.

Volunteers needed

A neuropsychiatric research project on personality disorders requires healthy female subjects between the ages of 18 and 45. Study involves screening evaluation, neuropsychological testing, and single-dose administration drug studies. There is limited risk and no radiation exposure. Payment is provided for participation. Call Dr. Eric Watsky at 202-373-6112. His e-mail address is watskye@dirpc.nimh.nih.gov.



Dr. Irwin Feuerstein, CC Department of Diagnostic Radiology, instructs his eight summer research students as they review x-rays to include in the students' WWW site project.

Web provides worldly venue for student project

The excitement is palpable. Enter the work room of Dr. Irwin Feuerstein's summer students. Energy bounces off the walls, laughter and ribbing intermingle with cyber-speak and medical terminology.

With a gang of eight visiting students, ranging in educational experience from high school to medical school, Dr. Feuerstein, CC Department of Diagnostic Radiology, has pioneered an innovative teaching project. It's where medicine meets the Internet. The students worked independently and as a team to create a world wide web (WWW) site, which functions as an electronic textbook.

The student-designed site,

composed of electronic (digital) pages, contains digitized images of x-ray films and written explanations of presented cases. Each page contains an explanation of the ailment or injury illustrated by the x-ray. The diagnosis is given but there are no entries for prognosis. The combined pages resemble an encyclopedia of radiology cases.

Dr. Feuerstein guides the research, dictates pertinent medical information about the cases, and obviously enjoys the interchange between students and doctor. "I'm surrounded by young minds, exceptional students, and creativity," Dr. Feuerstein says of his mentoring-physician experience.

Avi Mazumdar, Matthew Curley, Christopher Hinkle, Paul Wiegel, Audrey Adams, Stephen Chen, Michael Meadors, and Malena Moshesh make up the heterogeneous club of multi-talented minds.

"These are the people who did the work. They typed every letter, did the research, created every link, digitized every picture, and fashioned the site," Dr. Feuerstein says with a dramatic sweeping gesture toward the students.

Their different skill levels and experiences join forces to achieve a common goal, creating a successful radiology web site and launching it on the Internet. As Dr. Feuerstein points out, in this activity, "both the radiologists and the students are precariously poised on the learning curve."

"I entered on duty on May 15, along with Paul Wiegel," says Christopher Hinkle, a 21-year-old biomedical engineering student at Case Western Reserve University, "and for four weeks we set up the web site and created a framework to build the teaching file. My job has been to handle most of the computing aspects of the project."

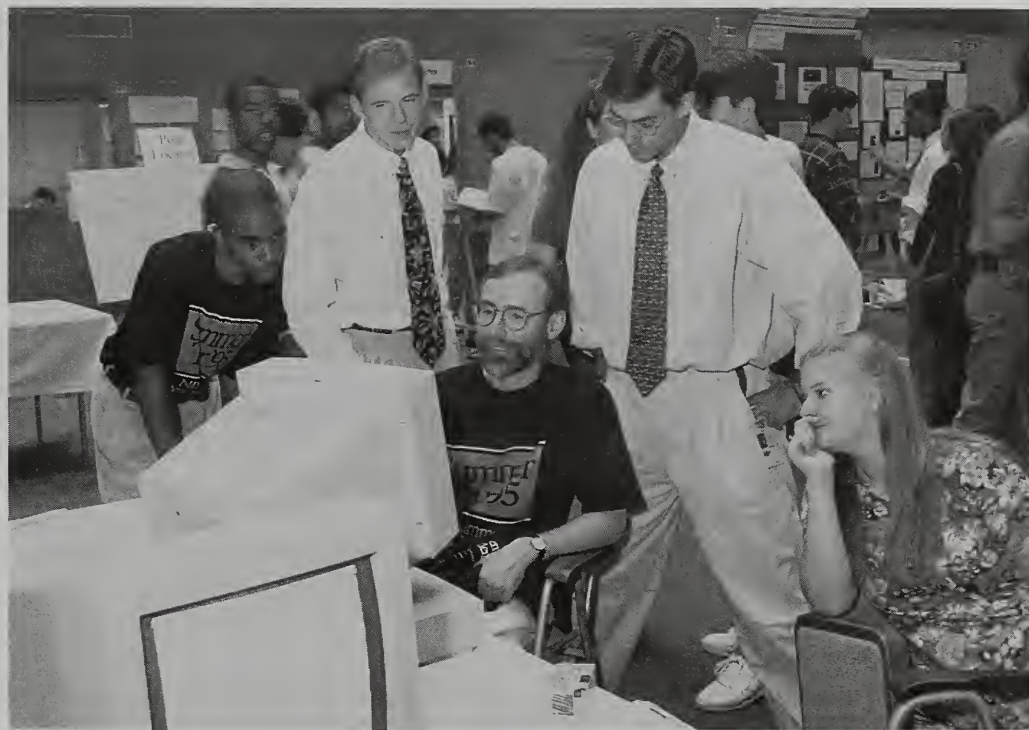
Malana Moshesh, third-year medical student at Howard University, spent considerable time editing and reconstructing the text and cases of her fellow students.

For the culminating activity, she helped create the poster that represented the team's accomplishments at the NIH Summer Research Program Poster Day 1995 held on last month.

The NIH Office of Education actively sponsors summer programs for students at all levels, from high school through graduate school and beyond. This year, the CC hosted approximately 80 summer students. There were 37 research students who worked in the Clinical Pathology, Diagnostic Radiology, Rehabilitation Medicine, Transfusion Medicine, Nursing, Nutrition, Pharmacy, and Social Work Departments as well as the bioethics program. This on-line teaching file is a project that Dr. Feuerstein hopes to continue with incoming students replacing the



Summer research students (from left) Michael Meadors and Avi Mazumdar update their WWW page as Paul Wiegel and Stephen Chen discuss x-rays to include in the radiology web site.



Kenneth J. Williams, Chris Hinkle, Matthew Curley, and Audrey Adams look on as Dr. Michael Fordis, NIH Office of Education director, test drives the Department of Diagnostic Radiology's student Wide World Web site at the NIH Summer Research Program Poster Day 1995.

current ones after they return to school.

"Our purpose was to provide stimulating research opportunities for students—to turn them on to research," explains Dr. Feuerstein. "I think we succeeded in that."

—by Laura Bradbard

CC pharmacist focuses on the human side of drug therapies

Clinical Center pharmacist Jim Minor looks for the questions in a patient's eyes.

After the bustle of inpatient rounds with CC and NIAID physicians, he goes back to those unspoken worries, sits down, and talks the patient through the whys and hows and what ifs of drug therapies.

"I learned real quick that there are always more questions than answers because of the nature of what we do here," he says. But he's also discovered that the beauty and challenge of working here is searching for those answers as part of an interdisciplinary health-care team.

Minor, 1995 recipient of the prestigious PHS Career Achievement in Pharmacy Award and the Award for Excellence in Clinical Pharmacy from the Association of Military Surgeons of the U.S., is a co-investigator or collaborator in many active research protocols. As a clinical pharmacy specialist, Minor's professional focus is on the therapeutic aspects of selecting a particular medicine for a specific patient.

"The ultimate goal," he explains, "is quality patient care. We work with medical fellows and senior staff to select the appropriate medicine and individualize all patient regimens."

That tailoring of drug therapies is important. Consider, for example, Interleukin-2, a drug that's being evaluated for its ability to modulate the immune system in patients with cancer or HIV. It can also cause sleep disturbances, skin rashes, nausea, vomiting, and anxiety. "Pharmacists can suggest other medications to

manage those symptoms and improve the comfort levels of patients going through protocols involving IL-2 and other potent drug therapies."

The profession and practice of pharmacy have evolved, particularly over the past decade, Minor points out. "Pharmacists have always been perceived as integral members of the medical care team by providing quality distributive services—making sure patients get the right medicines in the right dosages at the right time."

That's still a crucial function, he says, one that provides a foundation for the pharmacists' expanding roles in patient care.

"[My] colleagues in the Pharmacy Department work very hard to provide 24-hour pharmacy support services and to maximize both the quantity and quality of pharmaceutical care provided to CC patients.

"Seeing research protocols progress from inception in the lab to implementation on the patient-care floors and then on to become accepted standards of care—it's very gratifying to be a part of that."

And it's gratifying to share the experience. "I enjoy working with pharmacy students and residents," he says. "I want them to always think about the patients, and be able to understand and communicate the complex. I enjoy challenging our residents with difficult concepts of pharmacology on disease management issues, and answering their questions with questions of my own. It really makes them think, learn, and apply what they learn."

Minor's NIH career began in 1970 when he served a short rotation here as a pharmacy resident fresh out



CC pharmacist Jim Minor was honored with two major professional awards recently.

of the University of North Carolina. He went on to other PHS assignments in New England, southern California, Washington, and Hawaii and to earn a doctorate in pharmacy at the University of Southern California. Minor, a native of North Carolina, returned to the CC in 1981 where he has served as a member of the pharmacy department's cadre of clinical specialists. Minor now works primarily with NIAID investigators.

He's also an editor for the *American Journal of Health-Systems Pharmacy*, and co-edits with colleague Robert DeChristoforo "AIDS Facts," a feature designed to provide concise information about HIV research and evolving concepts of HIV management for pharmacists in the field.

"There are always more questions than answers," he says, "but you learn to ask the right ones and prioritize the search for answers. And our efforts contribute to a happier, healthier patient, and to the advancement of research."

—by Sara Byars

... collaboration has advanced gene therapy

Continued from page one

CC Director Dr. John I. Gallin, an authority on CGD and associate investigator on that study, was present at the infusion of gene-corrected cells into the patient. "After 20 years of working on this disease, it was very exciting," he says. He points out that this patient represents another unique aspect of the CC. "Most centers are lucky to have one or two CGD patients," he says. "Here we follow 80." Since no two gene therapy protocols are exactly alike, even for the same disease, having such a large group made it easier to select the most suitable patient for this particular trial.

Although the investigators have noted objective evidence of success in their patient, they are mindful of being overly optimistic and stress that gene therapy is a long way from being a cure-all for hereditary diseases. (See sidebar.) Dr. Gallin puts it in perspective: "If we simply do no harm, the trial will be a success; if we correct just one cell, the trial will be a huge success."

"No other transfusion service or blood bank in the world has access to the research resources that are available to us here."

Collaboration among CC staff, institute researchers, and private industry has advanced the technology supporting gene therapy as well. For example, in the 1990 trial, a system of plates and wells was used to combine the gene with the target cells. Since much handwork was needed, the chances of contamination rose with each manual intervention. Says Dr. Malech, "We are trying to create a completely closed system of

interconnected sterile bags and tubes through which cells would be processed." The only point of entry would be the initial blood draw from the patient.

"It's not totally closed yet—we simply don't yet have the technology," says Dr. Klein. "But depending on the protocol, we can now reduce the number of openings into the system from several hundred to under ten." This success has been hastened by Cooperative Research and Development Agreements between DTM, individual researchers, and Baxter Healthcare Corporation, a leader in health-care products, systems, and services.

DTM continues to set the standard for gene therapy. Researchers worldwide come here to be trained in the department's stringent techniques. DTM will soon submit a methods paper to the journal *Transfusion* so that others interested in gene therapy will have access to the procedures and technology developed here.

—by Sue Kendall

Gene therapy: Available soon at a hospital near you?

"I only wish that were the case," says Dr. Harry Malech, NIAID principal investigator on the CGD gene therapy trial. Asked about people's expectations for gene therapy, Dr. Malech replies that he takes great pains to give his patients a realistic picture of its potential risks and benefits. But, "even the very informed general public thinks [gene therapy] is right around the corner," he says. "When expectations are high and they're not immediately fulfilled, some think that either people aren't trying hard enough or the effort has no merit."

CC Director Dr. John I. Gallin points out that many practical roadblocks exist. "It's very expensive, and the number of different people needed is incredible. Most hospitals don't have the personnel, the money, or the time." Although NIH has more of these resources, pieces of basic science are still at large. But, Dr. Malech asks, "should we stop and wait just because we're missing some tools?"

Dr. Malech relates an anecdote about reading to his young son about the travails of pioneers on the Oregon Trail. The boy asked, "Why didn't they just wait for jet planes?" His father replied that most people did sit back and wait. Those who set out along the Trail were either great adventurers or out-of-luck people who took a chance that life elsewhere might be better.

"We too have to do the adventure," says Dr. Malech. "If we all sit and wait for the equivalent of jet planes, our patients won't live to see it happen."

... Daniels to become pharmacy chief Oct. 1

Continued from page one

Minnesota since 1980 and was director of graduate studies in hospital pharmacy there from 1982 to 1987.

In the mid-seventies, Dr. Daniels was at the Clinical Center as a pharmacy resident and later served as a staff pharmacist. While here he helped develop the unit-dose drug distribution system and provided patient-care services in the cardiovascular surgery unit.

In making his announcement, CC Director Dr. John I. Gallin said, "Dr. Daniel's expertise in management of distributive and clinical pharmacy and his active participation in pharmacy research make him ideally suited to lead the Pharmacy Department."

Dr. Daniels said that he looks forward to rejoining the rich tradition

of Clinical Center research and collaboration with NIH investigators, adding that he believes safe, efficient pharmacy operations must complement optimal drug therapy management and that the Pharmacy Department must place importance on these objectives.

"The department must focus on the quality of the services it provides to Clinical Center patients. Strong pharmacy services are essential to world-class patient care and premier research results," he says.

A fellow of the American Society of Health-System Pharmacists and active in that organization, Dr. Daniels received the Minnesota Society of Hospital Pharmacists Research Award in 1984 and 1986.

He currently serves on the advisory committee of the United States Pharmacopeial Convention,

Inc. Former contributing editor for the *International Pharmaceutical Abstracts*, he has just completed service on the editorial board of the *American Journal Of Health-System Pharmacy*, a position he held since 1983. Dr. Daniels also provides manuscript review for the *American Journal of Health-System Pharmacy* and *Hospital Formulary*.

Author of more than 40 articles, books, and other professional publications, Dr. Daniels graduated from the University of Arizona in 1975. He completed an American Foundation for Pharmaceutical Education fellowship at the University of Minnesota in 1979 and holds a master's in pharmacy and a Ph.D. in social and administrative pharmacy from the university.

Dr. Daniels is married and is the father of two teenagers.

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**Grand Rounds
noon-1 p.m.**

Lipsett Amphitheater

Insulinomas: Diagnostic and Therapeutic Strategies, Monica C. Skarulis, M.D., NIDDK; *G-whiz, Not Another Hepatitis Virus? The Cloning and Clinical Significance of the Hepatitis G Virus*, Harvey J. Alter, M.D., CC

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**Wednesday Afternoon
Lecture
3 p.m.**

Masur Auditorium

Aspirin in the Secondary and Primary Prevention of Cardiovascular Disease, Charles H. Hennekens, M.D., Dr.P.H., Harvard Medical School. The first annual Robert S. Gordon Lecture. Hosted by the Epidemiology Interest Group

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**Wednesday Afternoon
Lecture
3 p.m.**

Masur Auditorium

Mechanisms of Estrogen Action on Bone at the Tissue, Cellular, and Molecular Levels, B. Lawrence Riggs, M.D., Mayo Medical School. Hosted by the Clinical Research and the Hard Tissues Disorders Interest Groups

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**Grand Rounds
noon-1 p.m.**

Lipsett Amphitheater

Multidrug Resistance as an in vivo Selectable Marker for Gene Therapy, Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH; *Signal Transduction Therapy from Bench to Bedside*, Elise C. Kohn, M.D., NCI

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**Grand Rounds
noon-1 p.m.**

Lipsett Amphitheater

Gene Transfer to Hematopoietic Stem and Progenitor Cells: Progress and Problems, Cynthia E. Dunbar, M.D., NHLBI; *Breast Cancer: New Therapeutic Approaches*, Kenneth H. Cowan, M.D., Ph.D., NCI

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**Clinical Staff Conference
noon-1:30 p.m.**

Lipsett Amphitheater

Studies of Early Arthritis: Implications for Understanding Pathogenesis and Improving Management, H. Ralph Schumacher, M.D., NIAMS, moderator